

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference P200201190 WO | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/DK 03/00568 | International filing date (day/month/year) 01.09.2003 | Priority date (day/month/year) 02.09.2002 |
| International Patent Classification (IPC) or both national classification and IPC A61M39/00 | | |
| Applicant UNOMEDICAL A/S ET AL. | | |

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| <ol style="list-style-type: none"> 1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 7 sheets, including this cover sheet. <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 4 sheets.</p> | |
| <ol style="list-style-type: none"> 3. This report contains indications relating to the following items: <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the opinion II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application | |

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| Date of submission of the demand 01.04.2004 | Date of completion of this report 14.07.2004 |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | Authorized Officer Lager, J Telephone No. +49 89 2399-2957 |



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/DK 03/00568

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-5 as originally filed

Claims, Numbers

1-7 received on 18.06.2004 with letter of 15.06.2004

Drawings, Sheets

1/4, 3/4, 4/4 as originally filed

2/4 received on 18.06.2004 with letter of 15.06.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 03/00568

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application,

claims Nos. 1-4,7

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):

the claims, or said claims Nos. 1-4,7 are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

the written form has not been furnished or does not comply with the Standard.

the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------|-------------|-----|
| Novelty (N) | Yes: Claims | 5-6 |
| | No: Claims | |

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|---------------------|-------------|-----|
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 5-6 |

| | | |
|-------------------------------|-------------|-----|
| Industrial applicability (IA) | Yes: Claims | 5-6 |
| | No: Claims | |

2. Citations and explanations

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/DK 03/00568

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/DK03/00568

Section I.5

1. It appears to be no basis in the originally filed application, Article 34(2)(b) PCT, for the deletion of the passage "arranged diametrically opposite the groove (12)" from claims 1 and 7 which otherwise correspond to originally filed claims 1 and 6. There is no indication suggesting that any positioning is possible or that the above mentioned positioning is optional.
 - 1.1 The applicant has indicated that a basis may be found at page 5, lines 1-15. However this passage refers to figures 3a and 3b where the positioning of the protrusion and the groove is arranged as defined in originally filed claims 1 and 6.
 - 1.2 Therefore the assessment under Section III and V below has been done on the basis that above mentioned deletion never took place.

Section III.

1. Claims 1-4 and 7 do not contain any or sufficient information regarding how the folding of the tubing may occur, Article 6 PCT.
In the claims it is defined that the tube shall comprise a longitudinally extending external groove (12) and an external protrusion (11) where the groove and the protrusion are arranged on diametrically opposite sides of the tube. Should the skilled reader try to fold such a tube he will be confronted with the problem that the groove or protrusion will face each other disabling any connection. It appears to the examining division that each fold must be performed with a back-and-forth 180° turn of the tube with each folding turn in order to mate the groove with the protrusion. However, following experience this is not possible without kinking of the tube which will render the tube occluded. It may be that it could be possible with some very particular material, however, there are no indications in these claims suggesting such a material.
- 1.1 Since the description is silent regarding above mentioned problem the application is regarded as not sufficiently disclosed since the skilled reader cannot find the necessary information enabling him to carry out the proposed invention, Article 5 PCT.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/DK03/00568

- 1.2 With regard to claims 1-4 and 7, the application does not fulfil the requirements of Articles 5 & 6 PCT.
2. The objection to lack of unity raised by the search authority has not yet been examined.
3. Although claims 1, 5 and 7 (see "...in particular for use in connection with...") have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter, i.e. overlapping scope, and to differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of that subject-matter.

The aforementioned claims therefore lack conciseness.

Hence, claims 1, 5 and 7 do not meet the requirements of Article 6 PCT.

Section V

1. The closest prior art, with respect of claim 5, is represented by document US-A-5 522 803 (=D1) which discloses a device according to the preamble of claim 5.
 - 1.1 Claim 5 therefor fulfils the requirements of Article 33(2) PCT.
 2. The difference between the disclosure of D1 and the subject-matter of claim 5 is defined in the characterising portion where it is defined that the device should comprise a holder device for securing the tubing with at least two parallel grooves for receiving and securing the tubing in a releasable manner and that the tube will be in at least two parallel courses when folded and with a first and second end extending therefrom.

In claim 6 it is defined that folding will be in at least three parallel courses.

- 2.1 The objective technical problem solved with the difference of claims 5 and 6 over the teaching of D1 is therefore regarded as providing a holder which allows folding to the tube in parallel courses and in a secured and releasable manner.
- 2.2 If the skilled man in the art would be confronted with the problem of securing and folding the tube of D1 in a releasable manner he would turn to any of documents

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/DK03/00568

DE-A-26 20 009 (=D2) or EP-A-0 916 361 (=D3) which would lead him to a device according to the present wording of claims 5 and 6 without exercising inventive skill, contrary to the requirements of Article 33(3) PCT.

Both D2 and D3 discloses tube holding devices with holders which allows folding to the tube in a secured and releasable manner in at least two or three parallel courses, see figures 1 and 2 of D2 and the figure of D3, where the ends are extending therefrom.



Revised 15.06.04

DT15 Rec'd at CT/PTO 06 DEC 2004

1

Claims

1. A device for subcutaneous administration of a medicament to a patient, comprising:

- 5 - a cannula housing (1) with an interior chamber;
 - a cannula (2) connected to the cannula housing (1) and being in flow communication with the interior chamber;
 - a tubing (4) manufactured from a flexible material and having a first end (4') and a second end (4''), wherein the tubing (4) is, at the first end (4'), coupled 10 to the cannula housing (1) in such a manner that the tubing (4) is in flow communication with the interior chamber; and wherein the tubing (4), at the other end, carries a source coupling (5), by which the tubing (4) can be coupled to a source for said medicament,

characterised in

- 15 - that, at least over a part of its length, the tubing comprises a longitudinally extending, external groove (12) and a longitudinally extending, external protrusion (11) complementary with said groove (12); and
 - that, using the flexibility of its material, the groove (12) is configured 20 for being able to receive and secure the protrusion (11) in a releasable manner in a configuration of the tubing (4), in which the tubing (4) is folded (9) for forming parallel courses of tubing (14, 24, 34).

2. A device according claim 1, said external protrusion (11) being arranged 25 diametrically opposite the groove (12).

3. A device according to claim 1 or 2, **characterised in** that the tubing (4) with the groove (12) and the protrusion (11) is manufactured by extrusion of a plastics material.

Revised 15.06.04

4. A device according to the preceding claim, **characterised in** that the protrusion (11) is dovetail-shaped.

5. A device for subcutaneous administration of a medicament to a patient, comprising:

- a cannula housing (1) with an interior chamber;
- a cannula (2) connected to the cannula housing (1) and being in flow communication with the interior chamber;
- a tubing (4) manufactured from a flexible material and having a first end (4') and a second end (4''), wherein the tubing (4) is, at the first end (4'), coupled to the cannula housing (1) in such a manner that the tubing (4) is in flow communication with the interior chamber; and wherein the tubing (4), at the other end, carries a source coupling (5), by which the tubing (4) can be coupled to a source for said medicament,

15 **characterised in**

- a holder device (10) for securing the tubing (4) in a configuration in which the tubing (4) is folded for forming at least two parallel courses of tubing (14, 24, 34) with said first end (4') and said second end (4'') extending therefrom, and
- 20 - said holder device (10) comprising a plate with at least two parallel grooves (12) configured for being able to receive and secure said courses of tubing (14, 24, 34) in a releasable manner in said configuration of the tubing (4).

25 6. A device according to any one of the preceding claims, **characterised in** that the tubing (4) is folded for forming at least three essentially parallel courses (14, 24, 34) of tubing.

30 7. An extruded flexible tubing, in particular for use in connection with a device according to one of the preceding claims 1-4, **characterised in**

Revised 15.06.04

3

- that the tubing (4) is, at least over a part of its length, provided with a longitudinally extending, external groove (12) and a longitudinally extended protrusion (11) complementary therewith; and
- that, using the flexibility of the tubing (4), the groove (12) is configured for being able to receive and secure the protrusion (11) in a releasable manner in a configuration of the tubing (4), in which the tubing (4) is folded for forming parallel courses (14, 24, 34) of tubing.

2/4

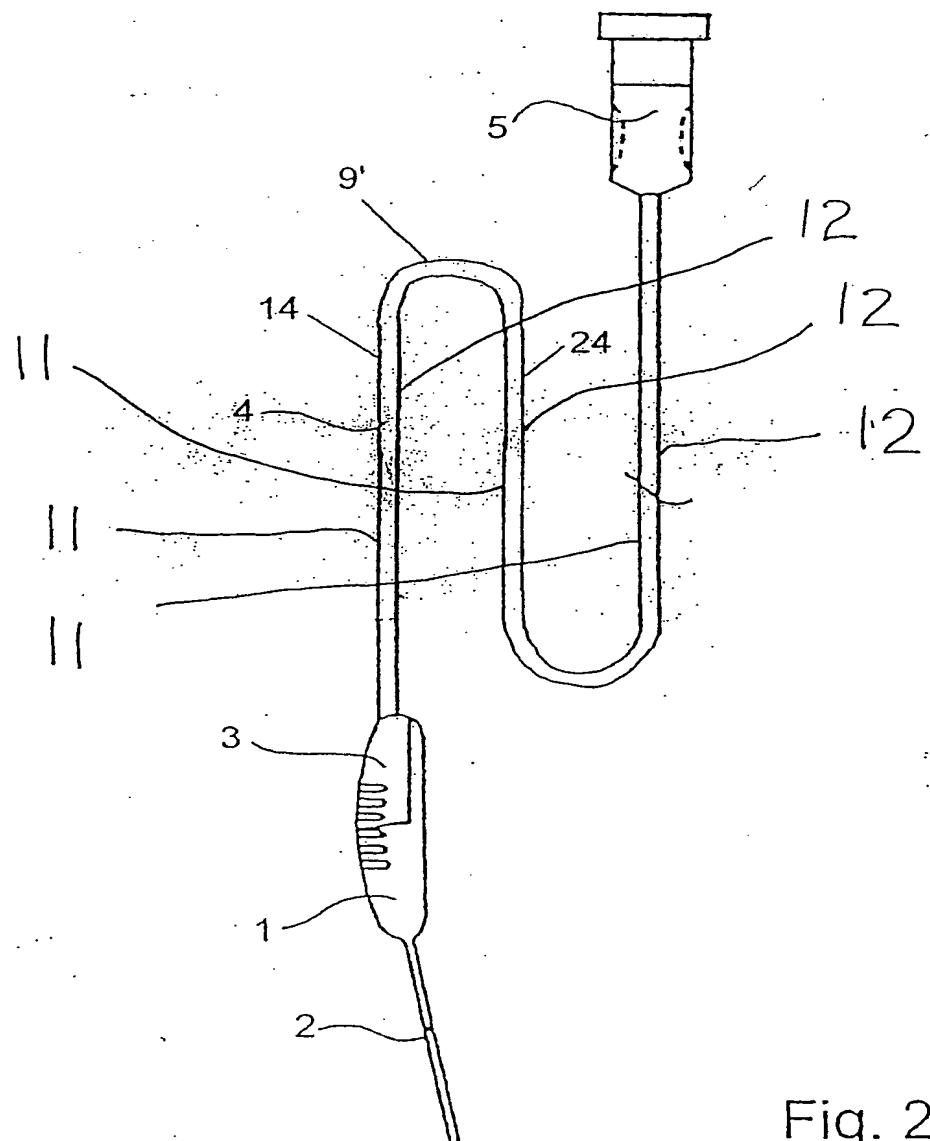


Fig. 2

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